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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KIM, YOUNG J

ART UNIT PAPER NUMBER

1637

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M

Office Action Summary

Application No.

09/802,472

Applicant(s)

EINAT ET AL.

Examiner

Young J. Kim

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 17 is/are allowed.
- 6) ☒ Claim(s) 9 and 13-15 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This Office Action responds the Amendment received on January 15, 2004.

Claim Objection – Maintained

The objection of claim 9 for depending on a subsequent claim, claim 13, made in the Office Action mailed on August 15, 2003 is maintained for the reasons of record. Applicants remark received on January 15, 2004 is noted. However, as the application is not in condition for allowance, the objection will be maintained hereto until the application becomes in condition for allowance and the claims renumbered (MPEP 608.01(n)).

Claim Rejections - 35 USC § 112

The rejection of claims 13, 9, 14, and 15 under 35 U.S.C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on August 15, 2003 is withdrawn in view of the Amendment received on January 15, 2004, amending the claims.

Rejections – Necessitated by Amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 9, 14, and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The present rejection is necessitated by Applicants' amendment to claim 13, wherein the amendment introduces the phrase, "wherein the protein encoded by said naturally occurring

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polynucleotide induces cell apoptosis when overexpressed in human epithelial breast carcinoma MCF-7 cells.”

Claim 13 and its dependent claims 9, 14, and 15 are indefinite for the recitation of the phrase, “said naturally occurring polynucleotide,” because claim 13 recites two instances of a naturally occurring polynucleotide, one of which is a “naturally occurring polynucleotide having at least 70%” and the second of which is a “naturally occurring polynucleotide of (i).”

Therefore, the claim amendment reciting, “said naturally occurring polynucleotide,” raises confusion in which of the two possible polynucleotides the term is referring to, rendering the claims vague and indefinite.

Necessitated by Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a Written Description Rejection.

The present rejection is necessitated by Applicants’ amendment to claim 13, wherein the amendment introduces the phrase, “a fragment of (a) or (b) which induces cell apoptosis when overexpressed in human epithelial breast carcinoma MCF-7 cells” (amendment underlined).

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By way of present amendment, Applicants claim any fragment of a protein or the protein's variant which induces cell apoptosis when overexpressed in MCF-7 cells. However, it is determined that Applicants had not possessed such fragment that induces cell apoptosis when overexpressed in MCF-7 cells for the following reasons.

Claims 13, 13, 9, 14, and 15 encompass a genus of protein fragments which induce cell apoptosis when overexpressed in MCF-7 cells.

Regarding the written description requirement and genus claims, the current guidelines call for the following questions to be asked: (1) have a representative number of species been described by complete structure; and if not, (2) have a representative number of species been described by sufficient relevant identifying characteristics. In the instant case, there is only a disclosure of a gene 95 (identified as SEQ ID NO: 4, encoded by a polynucleotide of SEQ ID NO: 3). The specification discloses the identification of the polypeptide of SEQ ID NO: 4, encoded by the claimed polynucleotide of SEQ ID NO: 3, as being a protein product of 62 Kd (page 111, line 18). The specification discusses the overexpression of the gene's transcript, mRNA (page 111, lines 20-25) under 4-16 hours of hypoxic treatments (page 112, lines 1-4). The specification also discloses a vector containing flag-epitope-tagged gene 95, wherein the overexpression of the gene product is disclosed as affecting the growth rate of proliferating breast tumor cells (page 114, lines 1-6). The specification, however, provides (1) no protein **fragments** which induces apoptosis; and (2) no description of which region of the product encoded by gene 95 is involved in the induction of apoptosis.

Since a representative number of species have not been described by the specification to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

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application was filed, had possession of the claimed invention. Also, the decision in The Regents of the University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), is highly relevant to the claimed invention because the court held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so **in sufficient detail** that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "**such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.**" *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," **not a mere wish or plan for obtaining the claimed chemical invention.** *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

The specification does not give at least a description, structures, figures, diagrams, or formulas which identify a region of the protein responsible for inducing apoptosis in MCF-7 cells, but only employs the whole gene product of gene 95 in the method (as discussed above), failing to demonstrate to a skilled artisan that Applicants were in possession of at least a single fragment of protein comprising 70% identity to protein encoded by polynucleotide comprising SEQ ID NO: 3 or a polynucleotide that is 70% homologous to the polynucleotide comprising SEQ ID NO: 3, the fragment of which induces apoptosis in MCF-7 cells when overexpressed, resulting in only a, "mere wish or plan for obtaining the claimed," invention (The Regents of the University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997)).

Conclusion

Claims 16 and 17 are allowed. Claims 9, and 13-15 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

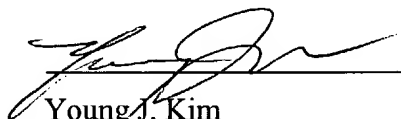
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

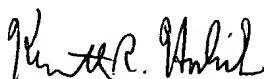
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should

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be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Young J. Kim
Patent Examiner
Art Unit 1637
3/25/04



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

4/1/04